

Upsher-Smith Laboratories, Inc.
Attention: Mark Robbins
14905 23rd Avenue North
Minneapolis, MN 55447-4709

FEB 11 2000

Dear Sir:

This is in reference to your supplemental new drug application dated September 17, 1999, submitted under 505(j) of the Federal Food Drug and Cosmetic ACT, regarding your abbreviated new drug application for Amiodarone Hydrochloride Tablets 200 mg

Reference is also made to your Tel Amendment dated 10/13/1999.

The supplemental application provides the Food-Effect Bioequivalence study data submitted per Agency letter dated April 1, 1999.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

/S/

for
Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

1/28/2000